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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,848	04/09/2004	Lawrence V. Tannenbaum	CHPPM 03-22 03	8673

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OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,848	TANNENBAUM, LAWRENCE V.	
	Examiner	Art Unit	
	JERRY LIN	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-29* is/are pending in the application.

4a) Of the above claim(s) *7-12,14 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 18-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed May 6, 2008, have been fully considered and they are deemed to be persuasive in-part. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Applicant's election of "mice" in the reply filed on October 28, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of the Claims

Claims 15, 16, 18-29 are under examination. (Claim 26 is examined as it is drawn to mice.)

Claims 7-12, 14, and 17 are withdrawn as being drawn to a non-elected invention or species.

Claim Rejections - 35 USC § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 15, 16, and 18-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the ecological risk to rodents, does not reasonably provide enablement for determining the ecological risk to other animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of assessing ecological risk for mammals by performing sperm analysis on rodents from a contaminated site and a reference site and comparing the results of the rodents from the different sites, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. For purposes of this rejection, the Examiner interprets the instant claims to mean that the determination or assessment is based upon the comparison of sperm count, sperm motility or sperm morphology.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary – since it is unknown whether the ecological risk to mice may be extrapolated to other mammals, a great deal of experimentation is needed.

(2) the amount of direction presented – the specification focuses on mice, but does not derive data from other mammals or teach how the data from mice applies to other mammals.

(3) the presence or absence of working examples – there are no working examples of data from mammals other than mice.

(4) the nature of the invention – the invention is drawn to assessing how mammals will react to a contaminated site. How an organism will react to environmental changes is unpredictable.

(5) the state of the prior art – the prior art does not show how the data from mice may be extrapolated to other mammals.

(6) the relative skill of those in the art – the level of skill of those in the art is high.

(7) the predictability or unpredictability of the art – extrapolating the results of one mammal to another different mammal is unpredictable.

(8) the breadth of the claims – the instant claims are drawn to assessing the ecological risk to animals.

The preamble and the final step of the independent claims, claims 1, 18, and 22 recite that the method assesses the ecological risk to mammals or determining the potential health effect to mammals. Giving the word "mammals" a broad reading, the claimed method determines the ecological risk to mammals other than mice. However, the method only examines data derived from mice. While it is clear that there the claimed method may measure the ecological risk to mice, the method may not measure the ecological risk to other animals. According to Working, factors such as genetic

variability, metabolism, intracellular pathways of toxicity, membrane biochemistry, absorption, distribution, storage, excretion, and specific organ function all contribute to major variability in responses to toxic chemicals (page 37, left column – page 38). In particular, Working states that the fertility of animal models may be an insensitive indicator of human reproductive risk (page 38, left column). The instant specification does not provide any data or rationale of why determining the ecological risk to mice may be extrapolated to assess the ecological risk to other mammals. Thus in order to determine the ecological risk to other mammals, one of ordinary skill in the art must perform undue experimentation.

Response to Arguments

5. Applicants have responded to this rejection by stating that other site mammals have home ranges that are significantly greater than test rodent species and have lesser degrees of exposure to contaminated media, Hazard Quotient (HQ) calculations may be adjusted for body weight, home range, and ingestion. Applicants contend that while the HQ may be adjusted, it is routinely assumed that the health effects in mice will also be displayed in the other mammals.

The instant claims state that the method is for assessing the ecological risk to mammals and generally determining the health of mammals at the site. HQ appears to a measurement of ecological risk according to the specification on page 1, paragraph 0005. Given that applicants have acknowledged that HQ must be adjusted for different mammals, the instant method would appear to require the same kind of adjustments to

extrapolate the data of mice to other mammals. However, neither the claims nor the specification teach how to extrapolate this data.

Applicants also state that it is assumed that all the mammals will develop the same health effects as the mice. This statement seems to contradict the applicant's reasoning for choosing mice as the test model. Mice are chosen because rodents burrow in the contaminated soil, eat contaminated vegetation, and drink contaminated water, typically do not migrate, and many generations of mice live in contaminated areas year after year. Thus, other animals do not have the same degree of sensitivity as other animals and are not chosen to be the test model. Because of this lack of sensitivity to the environment, these other mammals would be less likely to develop the same health effects as the mice. Furthermore, Working states that the fertility of animals models may be an insensitive indicator of human reproductive risk (page 38).

Applicants also point to the EPA guidelines for support. Section 6 of the remarks filed June 16, 2008, part A or B states that an agent or xenobiotic that causes reproductive effect in animal studies is assumed to pose potential reproductive threat to humans or other species. However, this statement is only addressed toward the agent or xenobiotic itself. This statement does not state how the agent or xenobiotic will affect humans if the agent is in the environment. For example, while the agent may be toxic to both humans and mice, humans may not be exposed to the agent if the agent is located in an environment only accessible to mice. Furthermore, part C, of section 6 of the remarks, only addresses humans, whereas the instant claims broadly assesses mammals in general.

Finally, applicants state that no one knows how much exposure is required to trigger comprised sperm parameters, and it is correct to assume that the requisite exposures are present to trigger sperm and other reproductive effects in the site mammals. The Examiner agrees this is true for the model animal, however this may not be true for other mammals which do not have the same degrees of exposure because of body weight, home range, ingestion, and etc.

Withdrawn Rejections

6. Applicant's arguments and amendments, filed May 6, 2008, with respect to the rejections made under 35 U.S.C. §112, 2nd and §103 have been fully considered and are persuasive. The amendments are sufficient to overcome the rejections made under 35 U.S.C. §112, 2nd. The declaration filed on May 6, 2008 under 37 CFR 1.131 is sufficient to overcome the Ieradi et al. reference in the rejections made under 35 U.S.C. §103. These rejections have been withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, Art Unit 1631
2/2/09